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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,787	07/28/2003	Slobodan Dan Dimitrijevich	0684CG.034678/DIV	5209

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,787	DIMITRIJEVICH, SLOBODAN DAN	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,25 and 27-34* is/are pending in the application.

4a) Of the above claim(s) *25 and 27-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election, new power of the attorney and request for extension of time, all filed 02/10/2005.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9 in the reply filed on 02/10/2005 is acknowledged. The traversal is on the ground(s) that a thorough search of the subject matter of claims 25 and 27-34 as well as claims 31-34 would necessarily include all art classifications 424 and 435, and searching of all the Groups would impose no additional burden on the patent office. This is not found persuasive because the three Groups are distinct from each other because the methods of Groups II and III requires fibrin glue along with the product which is not a requirement for the product of Group I; and the product of Group I require engineered fibroblasts that not required by the methods of Groups II and III. Furthermore, the product of Group I has different use than preventing tissue adhesion as in Group II or enhancing wound healing as in Group III because it can be used for cell culture. Regarding applicant argument that no burden on the patent examiner in searching the three groups, the examiner position is that the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, but are extensive since the patent examiner searches the databases mostly literally. Rarely

do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 25, 27-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim.

Claims 1-9 are included in the prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The present claims directed to product comprising collagen and component from cells.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,223,420 ('420).

US '420 disclosed patch comprising collagen type I, elastin and fibronectin, which reads on cell component from fibroblast (example 5).

5. Claims 1, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,842,477 ('477).

US '477 disclosed patch or film comprising collagen and engineered fibroblasts col.5, lines 4-6; col.7, lines 53-55; col.9, lines 8, 60-63).

6. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,596,304 ('304).

US '304 discloses collagen-based material to prevent post surgical adhesion comprising mixture of collagen I and III, and fibroblasts (abstract; col.4, lines 23-26; col.6, lines 3-7; col.8, lines 64-65; col.9, lines 18, 23-27; col.10, lines 6-7).

7. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0015724 ('724).

US '724 disclosed non-adhesive composition that can be in the form of film comprising collagen type I and III, and connective tissue growth factor and/or fibronectin (abstract; paragraphs: 0029-0031, 0036, 0038, 0064, 0073).

8. Claims 1, 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0028243 ('243).

US '243 disclosed film used as a prevention adhesion barrier comprising collagen, elastin and fibroblast (abstract; paragraphs: 0078, 00172, 0231; example 18).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,451,032 ('032) in view of US 6,077,987 ('987).

US '032 teaches film of collagenous material that prevents post surgical adhesion (abstract). The film comprises mixture of collagen type I and III (col.4, lines 30-36).

US '032 does not teach inclusion of cellular component into the film.

US '987 teaches method for enhancing the efficacy of tissue repair and promoting wound healing using engineered cells in a protein matrix (abstract; col.4, lines 5-13). The engineered cells are fibroblast from epidermal cells (col.4, lines 35-38, 45-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide collagenous film comprising collagen I and III as disclosed by US '032, and add engineered dermal fibroblast as disclosed by US '987, motivated by the teaching of US '987 that the engineered cells enhance the efficacy of tissue repair and promote wound healing, with reasonable expectation of having collagenous film comprising engineered fibroblast that promote wound healing without adhesion between the healing wound the adjacent tissues, as desired by applicants.

12. Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '477 in view of US '032.

US '477 teaches patch or film comprising collagen and engineered fibroblasts col.5, lines 4-6; col.7, lines 53-55; col.9, lines 8, 60-63).

US '477 does not teach the other co-component.

US '032 teaches film of collagenous material that prevents post surgical adhesion (abstract). The film comprises mixture of collagen type I and III (col.4, lines 30-36).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide film comprising collagen and engineered fibroblast as disclosed by US '447, and use mixture of collagen types I and III as disclosed by US '032, motivated by the teaching of US '032 that the film comprising both types of collagen prevents post surgical adhesion, as desired by applicants, with reasonable expectation of having film comprising collagen types I and III and engineered fibroblasts that prevents post surgical adhesion with great success.

13. Claims 2 and 3 rejected under 35 U.S.C. 103(a) as being unpatentable over US '243 in view of US '032.

US '243 teaches film used as a prevention adhesion barrier comprising collagen, elastin and fibroblast (abstract; paragraphs: 0078, 00172, 0231; example 18).

US '243 does not teach types of collagen.

US '032 teaches film of collagenous material that prevents post surgical adhesion (abstract). The film comprises mixture of collagen type I and III (col.4, lines 30-36).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide film comprising collagen and fibroblast as disclosed by US '243, and use mixture of collagen types I or mixture of collage types I and III as disclosed by US '032, motivated by the teaching of US '032 that the film comprising both types of collagen prevents post surgical adhesion, as desired by applicants, with reasonable expectation of having film comprising collagen types I and/or III and fibroblasts that prevents post surgical adhesion with great success.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '420, US '304, US '724 or US '243 each in view of US '987.

US '420 teaches patch comprising collagen type I, elastin and fibronectin, which reads on cell component from fibroblast (example 5).

US '304 teaches collagen-based material to prevent post surgical adhesion comprising mixture of collagen I and III, and fibroblasts (abstract; col.4, lines 23-26; col.6, lines 3-7; col.8, lines 64-65; col.9, lines 18, 23-27; col.10, lines 6-7).

US '724 teaches non-adhesive composition that can be in the form of film comprising collagen type I and III, and connective tissue growth factor and/or fibronectin (abstract; paragraphs: 0029-0031, 0036, 0038, 0064, 0073).

US '243 teaches film used as prevention adhesion barrier comprising collagen, elastin and fibroblast (abstract; paragraphs: 0078, 00172, 0231; example 18).

However, the references do not teach the fibroblast cells to be engineered cells.

US '987 teaches method for enhancing the efficacy of tissue repair and promoting wound healing using engineered cells in a protein matrix (abstract; col.4, lines 5-13). The engineered cells are fibroblast from epidermal cells (col.4, lines 35-38, 45-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide film comprising collagen and fibroblast as disclosed by any of US '420, US '304, US '724 or US '243, and replace fibroblast by engineered dermal fibroblast as disclosed by US '987, motivated by the teaching of US '987 that the engineered cells enhance the efficacy of tissue repair and promote wound healing, with reasonable expectation of having film comprising collagen and engineered fibroblast that promote wound healing without adhesion between the healing wound the adjacent tissues, as desired by applicants.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER